



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-1146]

Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision-making. This guidance provides sponsors and other stakeholders with considerations when either proposing to design a registry or using an existing registry to support regulatory decision-making about a drug’s effectiveness or safety.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-D-1146 for "Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993-0002, 301-796-3161, Dianne.Paraoan@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” FDA is issuing this guidance as part of its RWE Program and to satisfy, in part, the mandate under section 505F of the FD&C Act (21 U.S.C. 355g) to issue guidance about the use of RWE in regulatory decision-making. Topics covered in this guidance include:

- A registry’s fitness-for-use for regulatory decision-making, focusing on attributes of a registry that support the collection of relevant and reliable data
- Considerations when linking a registry to another data source, such as data from medical claims, electronic health records, digital health technologies, or another registry
- Considerations for supporting FDA review of submissions, including registry data

Section 3022 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255) amended the FD&C Act to add section 505F, Utilizing Real World Evidence. This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help support or satisfy postapproval study requirements. This section also requires that FDA utilize the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for

collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. FDA is issuing this draft guidance as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI commitment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Real-World-Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910-0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572. The collections of information in 21 CFR parts 310 and 314 have been approved under OMB control number 0910-0230. The collections of information in 21 CFR parts 310, 314, 600, and 803 have been approved under OMB control number 0910-0291. The collections of information in 21 CFR parts 310, 314, 600, and 803 have been approved under OMB control number 0910-0645. The collections of information in 21 CFR part 312 have been approved

under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910-0308. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078. The collections of information in FDA’s guidance for industry entitled “Formal Meetings with Sponsors and Applicants for PDUFA Products” have been approved under OMB control number 0910-0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.